



FDA Deferral Update to Individual Donor Assessment Screening

FREQUENTLY ASKED QUESTIONS

1) When will the new FDA recommendations (Individual Donor Assessment) be implemented fully at ASBP donor centers?

This process is expected to take about six months for full implementation. Our goal is November 2023 with FDA requirements being no-later-than January 1, 2024. Implementation process involves full review and sign off by medical directors, updating the Blood Establishment Computer System (FDA regulated), validation of performance to ensure blood safety, new screening materials to include software updates and training and assessment of staff to support the correct protocols in all processes of interview, initial prescreen and more.

2) Why does it take this long to implement this?

The ASBP is committed to making the transition to the new screening protocols as quickly as possible, while maintaining the highest quality of safety for each donor and the patients who will receive their donated blood.

With any major updates to screening, deferral removal or additions, this process is the same; having to go through approvals, updates and training needed to fully implement.

We are grateful to donors and prospective donors of all ages and backgrounds who understand the importance of lifesaving blood donations and welcome them to our centers. The blood community remains committed to continuing to address barriers, further modify practices and policies, and to welcoming a diverse donor base that more fully and equally reflects and serves our military community.

3) For reference, what are the deferral questions the FDA has recently recommended eliminating?

The FDA recommends "...eliminating the screening questions specific to men who have sex with men (MSM) and women who have sex with MSM. Instead... [they are now recommending] assessing donor eligibility using the same individual risk-based questions relevant to HIV risk for every donor regardless of sex or gender." [Source: *Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*, FDA, May 2023]

4) What does the guidance specifically mean in terms of the deferral for donating blood?

Guidance would shift to a three-month deferral based on recent sexual contact with new partner(s) in addition to recent high-risk sexual activity in the past three months. Donors previously deferred for positive responses to screening questions specific to MSM, may be re-assessed for blood donation.



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5) Are there any additional updates to other deferrals based on the Individual Donor Assessment?

Newly issued FDA guidance recommends a three-month deferral from the most recent dose of an oral medication, such as a short-acting antiviral HIV pre-exposure prophylaxis drugs, otherwise known as PrEP, and a two-year deferral is recommended from the most recent injected version of the medication (i.e., long-acting antiviral PrEP). A permanent deferral is in place for an individual who has ever taken any medication to treat an HIV infection.

6) I have other questions. Where can I find more information about this?

Please reach out to your local ASBP donor centers to ask specific questions on deferral information and implementation.

You can also find additional materials to review and read more about on our site [here](#) and on the AABB* website directly at <https://www.aabb.org/news-resources/resources/individual-donor-assessment-resources>.

**AABB is the Association for the Advancement of Blood and Biotherapies; an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. The Association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. The ASBP is one of many blood programs that is connected to this blood banking and biotherapies community, on several task forces and committees.*